April 14, 2015

Senate Finance Committee
Business Income Tax Working Group
Business@Finance.Senate.gov

Dear Senator Thune and Senator Cardin:

On behalf of the Association of Clinical Research Organizations (ACRO,) thank you for the opportunity to comment on business tax reform. Our comment addresses the need to modernize of the R&D tax credit to recognize the important role contract research plays in the development of innovative, new medical products.

As the world's leading, global contract clinical research organizations (CROs) ACRO member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 110,000 employees engaged in research activities, each year ACRO member companies conduct more than 9,000 clinical trials involving nearly two million research participants in142 countries.

Clinical research is an economic driver in the United States. In the past 10 years, ACRO members have increased their payroll by 125 percent while increasing revenues 180 percent. This has occurred at the same time the pharmaceutical industry has been reducing its R&D staffs and shedding facilities in the search for greater efficiency.

Many of these staff have found a home in the CRO industry and our members have acquired several facilities from pharmaceutical companies over the past 10 years, enabling them to serve development projects from multiple sponsors and achieve high utilization rates. In fact, CROs today employ more clinical research professionals than the pharmaceutical industry, according to the Tufts Center for the Study of Drug Development.

Currently, approximately one-half of industry-sponsored clinical trials are conducted in the United States and most new drug trials are now multi-site, multi-regional in nature. Clinical research is conducted globally for several reasons: access to patient populations; disease prevalence; a desire to market drugs globally; access to physician investigator research networks; greater clinical trial participation rates outside the US; and economic incentives. Note also that the United States accounts for less than 6 percent of the world’s population though the market for pharmaceutical, biotech and medical device products is global.

Our comment focuses on a particular aspect of the IRC Section 45 R&D tax credit that should be modernized to reflect the new reality that much of the drug development

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process has shifted to contract researchers. The limited change we are advocating would provide contract research companies a similar, but much reduced, benefit that other companies receive today for in-house research. This minor change would provide an incentive to hire domestically, conduct more clinical trials here and continue to innovate in the United States.

Currently, providers of "contract research" services are not eligible to receive any portion of the R&D tax credit. Also, when the sponsor of the research, in our case generally a biopharmaceutical company, contracts with a CRO its eligible expenses for the credit are reduced from 100 percent to 65 percent. The remaining 35 percent is abandoned.

But in several countries outside the United States – such as France, Canada, the UK, Austria and others - the contract research provider is eligible for tax credits for their research expenses, sometimes receiving 100 percent of the credit, as the company that is employing the researchers. These countries, and much of the world, target the credit to the employer rather than the intellectual property owner. In fact, an estimated 70 percent of the expenses associated with the R&D credit are in the form of wages. This difference in approach places the United States at a distinct disadvantage as a venue for conducting innovative medical research and provides a perverse incentive for our members to locate clinical trials outside the United States.

The members of ACRO continue to be predominantly U.S.-based with roughly half of their employees and facilities in the United States. Over the past 10 years, our members have made significant investments purchasing domestic facilities and absorbing existing employees from pharmaceutical companies that were downsizing or restructuring their internal R&D staffs. This has occurred particularly in states such as Kansas, Pennsylvania, North Carolina, Indiana and Washington that have a large life sciences industry presence.

The net effect is that a facility where the employees were generating qualifying research expenses for a pharmaceutical company prior to the acquisition are no longer considered qualifying expenses for the new employer. This is an illogical result, particularly when you consider that many of these facilities were scheduled to be closed but for the acquisition by a contract research provider. After acquisition, significant investment is made to upgrade these facilities to accommodate business demand and the current science. As they come up to speed, they function at much higher capacity, adding jobs and serving multiple clients rather than only one, internal, client. Yet, the same expenses are no longer eligible for the R&D credit simply because the name on the pay check has changed.

The result is a disincentive to maintain and continue to hire research professionals and grow facilities domestically. Our members employ thousands of MDs, PhDs, PharmDs and nurses in well-paying research positions. The average annual U.S. salary across all employees of our member companies in in excess of $62,000.

(A brief animated explanation of this issue can be found by clicking here.)

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Fortunately, the bi-partisan COMPETE Act (S. 537) co-sponsored by Senator Carper and Senator Toomey would remedy this anomaly in the R&D credit to help ensure high-wage research jobs and medical innovation are supported in the United States. We expect bi-partisan legislation addressing this issue to be introduced in the House soon. While this provision has not received a specific score, we believe the cost to be minimal within the overall context of the R&D tax credit and that the benefits in terms of U.S. employment and innovation will far outweigh the modest cost.

Thank you for your consideration. We would be happy to provide additional information or answer any questions you may have. I may be reached at 202.464.9340 or jlewis@acrohealth.org.

Warmest Regards,

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